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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,372

10/26/2006

Minoru Kohara

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EXAMINER

SASTRI, SATYA B

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

01/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/584,372	Applicant(s) KOHARA, MINORU	
	Examiner SATYA B. SASTRI	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/06, 5/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to application filed on October 26, 2006. Claims 1-10 are now pending in the application.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on Jan. 7, 2004. It is noted, however, that applicant has not filed a certified copy of the JP2004-002491 application as required by 35 U.S.C. 119(b).

Specification

3. The disclosure is objected to for the following reasons:

(1) The word "amine" should appear once in line 1, page 14, of the specification filed on 6/23/06.

(2) The use of the trademark (such as those in paragraph 0039) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Art Unit: 1796

(3) The following guidelines illustrate the preferred layout for the specification of a utility application. Specifically, applicants are to note the placement of the brief description of the drawing in the specification. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

4. Claims 4, 5 and 7 are objected to because the claims do not clearly recite as to which elements of the group are required in the composition. Further, where applicable, a Markush type

Art Unit: 1796

recitation may be used (such in claim 7). When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. See MPEP § 2173.05(h).

In the instant office action, claim 4 is interpreted as including all three monomers given that hydroxyethyl (meth)acrylate is mandatory in claim 1.

Appropriate corrections are requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim is in regard to a composition but appears to include structural limitations.

Claim Rejections - 35 USC § 103

Art Unit: 1796

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (US 6,632,906 B1).

The prior art to Kamiyama concerns bioadhesives comprising an adhesive polymer, a plasticizer and a polyamine crosslinking agent wherein the amount of plasticizer ranges from 17 to 200% w/w of the adhesive. The crosslinking agent may range from 0.05 to 2% by wt. of the adhesive (abstract, col. 7, lines 23-27). Polyamine crosslinking agents are disclosed in col.6-7, bridging paragraph. The adhesive solution is mixed with the polyamine and then applied to the tape or the patch (col. 9, lines 42-52).

The adhesive compositions may further include compounds that have therapeutic, prophylactic or other beneficial pharmacological or physiological effects (col. 8, lines col. 8, lines 37-67, col. 9).

Working examples disclose adhesive compositions comprising a mixture of acrylic copolymer, plasticizer and a diamine compound to be coated on a PET films (Tables 24 and 25). The presently cited pseudo-crosslinking agent (as recited in instant claim 7) reads on the disclosed diamine compound.

The prior art does not disclose acrylic polymers with 3 to 25% by wt. of hydroxyethyl (meth)acrylate.

Art Unit: 1796

The prior art discloses that the acrylic polymers for use in transdermal patches include a polar monomers such as 2-hydroxyethyl acrylate, vinyl pyrrolidone, acrylamide etc. (col. 5, lines 30-38). Preferred monomers include diacetoneacrylamide or other polar monomer such as hydroxyethyl methacrylate or vinyl acetate, in amounts up to 50% w/w of the monomeric mix, order to enhance the solubility of certain drugs (col. 5, lines 49-55). Thus, it would have been obvious to one of ordinary skill in the art to utilize appropriate amounts of 2-hydroxyethyl acrylate depending upon the specific drug in the composition, including that within the presently claimed range and thereby arrive at the presently cited claims absent evidence of unexpected results.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (US 6,632,906 B1) in view of Holguin et al. (US 6,558,790 B1).

The discussion with regard to Kamiyama above in paragraph 8 is incorporated herein by reference.

The prior art is silent with regard to N-vinyl pyrrolidone in the adhesive copolymer composition.

Secondary reference to Holguin et al. discloses pressure sensitive adhesives comprising copolymers formed preferably from butyl acrylate (5-75% by wt.), 2ethylhexyl acrylate (5-45%), hydroxyethyl acrylate (20-50%) and optionally, N-vinyl pyrrolidone (up to 10%) (abstract, col. 2, lines 35-45, claims 1, 21). Further, given the teaching PSAs comprising such acrylic copolymers are water permeable and given that the PSA copolymer exhibits low adhesive edge lift when applied to skin (col. 2, lines 14-25), it would have been obvious to one of ordinary skill

Art Unit: 1796

in the art to include monomers taught by Holguin et al. in the acrylic copolymers of Kamiyama and thereby arrive at the presently cited claims.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satya Sastri at (571) 272 1112. The examiner can be reached on Wednesdays and Fridays, 7AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satya B Sastri/

Examiner, Art Unit 1796